WRITTEN STATEMENT

THE CASAC REVIEW OF THE OZONE AND PM STANDARDS

PRESENTED BY

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FOR THE

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SUMMARY

The selection of the an 8-hour ozone and a 24-hour and annual and $PM_{2.5}$ NAAQSs is consistent with the advice given to EPA by the Clean Air Scientific Advisory Committee (CASAC). The choice of the level of the ozone standard is consistent within the range endorsed by CASAC, but CASAC stated that the selection of a specific level within the range was strictly a policy judgment. CASAC panel members could come to no consensus on the appropriate ranges or levels for $PM_{2.5}$ standards.

In the closure report to the EPA Administrator, CASAC concluded that “the weight of the health effects evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure to ozone above background concentrations.” CASAC then reviewed EPA’s quantitative risk assessments. Although EPA’s analysis showed differences among the various standard levels, CASAC stated that “the ranges are not reflective of all of the uncertainties associated with the numerous assumptions that were made to develop the estimates.” As a result CASAC concluded: “there is no “bright line” which distinguishes any of the proposed standards (either the level or the number of allowable exceedences) as being significantly more protective of public health.” They further state: “Consequently, the selection of a specific level and number of allowable exceedences is a policy judgment.” This means that the decisions to select a given level or number of allowable exceedances within their proposed ranges cannot be based on science.

Having said that, eight members expressed their “personal preferences” for the level and number of allowable exceedances. All eight favored multiple exceedances. Three members preferred 0.08 ppm, three members preferred 0.09, one member said 0.08 or 0.09 ppm and one member said 0.09 or 0.10 ppm. The health effects experts were equally divided as well. Clearly, this is not an endorsement for a 0.08 ppm standard.

The 21 members of the CASAC PM review panel expressed a tremendous diversity of opinion and this is documented in Table 7 which is reproduced from the closure report. Pertaining to the 24-hour $PM_{2.5}$ NAAQS, only five members recommended a range which included 50 µg/m^3 or lower. Four members recommended greater than or equal to the top of EPA’s range. Four members did not recommend a 24-hour NAAQS. The remaining eight members merely endorsed the concept of a 24-hour $PM_{2.5}$ NAAQS, but declined to select a value or range. Also note from the Table that the diversity of opinion was exhibited by the health experts as well as the non-health experts. Clearly, this is not an endorsement of a 50 µ/m^3 standard.

For the annual standard, only two members favored a range that went as low as 15 µg/m^3. Two members favored 20 µg/m^3; one chose 20 - 30 µg/m^3; two chose 25 - 30 µg/m^3; and eight did not think an annual $PM_{2.5}$ NAAQS was needed. The remaining six members merely endorsed the concept of an annual standard but declined to select a value or range. This is not an endorsement of an annual $PM_{2.5}$ NAAQS of 15 µg/m^3.

LEGISLATIVE BACKGROUND

In 1963, the Clean Air Act (CAA) was passed by Congress directing the then Department of Health Education and Welfare to prepare “Criteria Documents” which would contain summaries of the scientific knowledge on air pollutants arising from widespread sources. The 1970 CAA required the EPA Administrator to set National Ambient Air Quality Standards (NAAQS) for the identified “criteria” pollutants and gave the Administrator the authority to revise the NAAQSs in the future and to set additional NAAQSs as needed. At that time, 6 air pollutants were designated as criteria pollutants: photochemical oxidants (later became ozone), sulfur dioxide, non-methane hydrocarbons (later dropped as a criteria pollutant category), nitrogen dioxide, carbon monoxide, and total suspended particulate (later changed to PM_{10} which includes only particles with an aerodynamic diameter less than or equal to 10 microns). In 1971, EPA established NAAQSs for all six.

The absence of a mechanism for a periodic reassessment of the initial NAAQSs, prompted Congress to add into the 1977 CAA amendments a requirement that the NAAQSs be reevaluated every five years. In addition, the 1977 amendments created a new committee -- the Clean Air Scientific Advisory Committee (CASAC), to review the periodic reevaluations. Organizationally, CASAC is housed within EPA’s Science Advisory Board (SAB)[1] and functions as one of the ten standing committees of the SAB. However, unlike most of the other standing committees of the SAB, CASAC reports directly to the EPA Administrator rather than through the Executive Committee of the SAB.

Congress specified a number of responsibilities for CASAC. One was to provide independent advice on the scientific and technical aspects of issues related to the criteria for air quality standards. The CASAC charter[2] states some of their functions:

> Not later than January 1, 1980, and at five year intervals thereafter, complete a review of the criteria published under section 108 of the Clean Air Act and the national primary and secondary ambient air quality standards and recommend to the Administrator any new national ambient air quality standards or revision of existing criteria and standards as may be appropriate.
>
> Advise the Administrator of areas where additional knowledge is required concerning the adequacy and basis of existing, new, or revised national ambient air quality standards.
>
> Describe the research efforts necessary to provide the required information.
>
> Advise the Administrator on the relative contribution to air pollution concentrations of natural as well as anthropogenic activity, and
>
> Advise the Administrator of any adverse public health, welfare, social, economic, or energy effects which may result from various strategies for attainment and maintenance of such national ambient air quality standards.

Previous activities of CASAC prior to 1985 have been summarized by Lippmann.[3]

Concerning the membership of CASAC, the charter states:

> The Administrator will appoint a Chairperson and six members including at least one member of the National Academy of Sciences, one physician, and one person representing State air pollution control agencies for terms up to four years. Members shall be persons who have demonstrated high levels of competence, knowledge, and expertise in the scientific/technical fields relevant to air pollution and air quality issues.

For any NAAQS review, a CASAC Panel is constituted to conduct the review. A Panel consists of the seven regular members plus a sufficient number of consultant members so that the broad spectrum of expertise needed to fully assess a particular issue is covered on the Panel. These consultants are generally selected from EPA's Science Advisory Board (SAB)[1] or from a pool of about three-hundred consultants maintained by the SAB. However, certain issues have required going outside of the SAB and the SAB consultant pool to obtain a particular expertise. For the ozoneNAAQS review, the panel consisted of fifteen individuals including physicians, epidemiologists, toxicologists, atmospheric scientists, plant biologists, risk assessment experts and an economist. For the PM review, the panel consisted of 21 scientists.

THE NATIONAL AMBIENT AIR QUALITY STANDARDS

There are two types of NAAQS: primary and secondary. Primary NAAQS are set to protect human public health. Secondary NAAQS are set to protect against adverse welfare effects which include protection of plants, animals, ecosystems, visibility, etc. Primary NAAQS are required to be set at a level that protects public health with an adequate margin of safety for the benefit of any sensitive sub-populations. This is the paradigm CASAC has operated under since it conception.

In considering the appropriate level for a secondary standard, cost/benefit analysis can be considered, and in fact, is generally the limiting factor in the selection of a secondary NAAQS.

THE OZONE REVIEW PROCESS

The major steps in the NAAQS review process are illustrated for ozone in Table 1. EPA began drafting the Criteria Document (CD), which summarizes all of the relevant science on the sources, chemistry, effects, etc. of ozone, in the middle of 1993. Recent Criteria Documents have become mammoth undertakings. The first ozone Criteria Document,[4] published in 1970, summarized the relevant science in 200 pages. The present Criteria Document[5] is a three volume set and contains over 1500 pages. A draft Criteria Document was sent to the CASAC Panel in June of 1994.

The Staff Paper (SP) contains the Agency's recommendations for the range and form of the NAAQS along with the justifications for the recommendations that are drawn from material contained in the Criteria Document. In the past, the CASAC review of a Criteria Document was completed before the Staff Paper was written so that the Staff Paper would reflect the science contained in the final Criteria Document. The reviews of both the Criteria Document and Staff Paper are iterative processes that usually involve two to three revisions to both of the documents before CASAC reaches closure, and, in the past, the entire process took several years to complete. However, this review was on an accelerated schedule because of a previous lawsuit filed by the American Lung Association (ALA). In the previous review, CASAC came to closure on the Staff Paper in 1989. When EPA failed to complete the last two steps listed in Table 1 by October of 1991, the ALA and other plaintiffs filed a suit to compel EPA to complete its review. The U.S. District Court for the Eastern District of New York subsequently issued an order requiring the EPA Administrator to announce its proposed decision by August 1, 1992 and its final decision by March 1, 1993. EPA's decision was to retain the existing 1-hour standard of 0.12 ppm, but noted that since there were many potentially important new studies published since the last Criteria Document was written, they would complete the next review of the ozone NAAQS as rapidly as possible. The ALA sought judicial review of this decision, but because of EPA's intention to complete the review as rapidly as possible, the ALA granted EPA a voluntary remand of the petition for review. To accomplish the accelerated review, some of the steps listed in Table 1 were conducted to some extent as parallel tasks rather than sequential tasks. In particular, a draft of the Staff Paper[6] was sent out for CASAC review in February of 1995 even though closure on the Criteria Document did not occur until November of 1995.

As shown in Table 1, CASAC reached closure[7] on the third revision of the Criteria Document in fifteen months. CASAC also reached closure[8] in November 1995 on the Staff Paper after a nine month review process and two Staff Paper revisions. The proposed NAAQSs were announced in the December 13, 1996 *Federal Register*. The last step in the process, EPA's promulgation, is scheduled to be published in the *Federal Register* on or before June 28,

1997. A public comment period for the December 1996 notice will close February 18, 1997.

HISTORY OF THE OZONE STANDARD

The history of the ozone NAAQS is summarized in Table 2. Additional details are contained in the Staff Paper.[6] In the Staff Paper, EPA recommended that the existing 1-hour NAAQS of 0.12 ppm be replaced with an 8-hour average NAAQS within the range of 0.07 ppm to 0.09 ppm with one to five allowable exceedances per year averaged over a three year period. The range of stringency from the most stringent (0.07 ppm with 1 allowable exceedance) to the least stringent (0.09 ppm with 5 allowable exceedances) is substantial. In the December 1996, notice, EPA proposed an 8-hour NAAQS of 0.08 ppm. To be in attainment, the average of the third highest in each year for three years could not exceed 0.08 ppm. At this level, the new NAAQS is significantly more stringent than the present 1-hour NAAQS when the resulting number of nonattainment areas are considered. With the present NAAQS, 68 Metropolitan Statistical Areas (MSAs) where ozone was monitored through September, 1996 did not meet the standard. This number would jump to 140 with the new 8-hr NAAQS of 0.08 ppm. However, this does not tell the entire story because many of the counties in between MSAs do not now have ozone monitors because they meet the present NAAQS. Some of these counties would become nonattainment with a more stringent NAAQS.

As pointed out in the Criteria Document[5] and the Staff Paper,[6] the 1-hour daily maximum background ozone averages between 0.03 to 0.05 ppm. This is the average 1-hour maximum ozone that could be expected during the summer in the continental U.S. in the absence of sources of anthropogenic precursor emissions in the U.S. In rural areas, which experience broader ozone peaks than urban areas because of the lack of ozone scavenger emissions, the maximum daily 8-hour background ozone concentration would be expected to be only slightly less than the 1-hour maximum background of 0.03 - 0.05 ppm. Consequently, with an 8-hour NAAQSs being considered, background ozone becomes a more important consideration.

OZONE HEALTH EFFECT STUDIES: RESULTS AND IMPLICATIONS

The ozone review relied mainly on four broad types of health effect studies: animal studies, controlled human chamber studies, field studies of ambient exposures, and hospital admission studies. The main use of the animal studies was to gain insight on the mechanisms by which ozone produces biological responses and damage to the respiratory system. In the controlled human exposure studies, individuals were typically exposed to ozone concentrations slightly above, at, or below the present NAAQS for a number of hours (~ 6 hours is the most common) while engaged in light to heavy exercise. Before, during and after the exposure the individual lung functions (such as FEV_1 which is the maximum volume of air that can be expired in one second) are monitored and any symptoms (cough, shortness of breath, chest pain, etc.) are noted. These studies have produced two important results. First, for one or two hour exposures, decrements in lung function tests and symptoms were noted in individuals not engaged in exercise <u>only at</u> concentrations greater than three times the present NAAQS. However, some exercising individuals experience decreased lung-function test performance and symptoms even at concentrations at or below the present NAAQS when exposed for multiple hours. This is one of the pieces of evidence that suggested a multiple hour (8-hours) NAAQS is a better measure of response than a 1-hour standard.

The field studies consisted of summer camp and adult exercise studies. In the summer camp studies, children, engaged in the normal physical activities that occur at summer camps, participated in lung function testing and the results were compared to the ambient ozone concentrations. In the adult exercise studies, lung function tests were administered to joggers before and after they ran outdoors and the test results were also compared to the ambient ozone concentrations. The results of both types of studies showed a small but statistically significant relationship between decreased performance on the lung function tests with increasing ozone at concentrations at and below the present NAAQS. These results are consistent with the controlled chamber studies and reinforce the evidence that an 8-hour NAAQS is a better measure of response than a 1-hour NAAQS. <u>Furthermore, since the relationship between the lung function test results and ozone appears to be linear, there may not be a threshold concentration below which biological responses will not occur.</u>

The hospital admission studies examined the relationships between daily ozone concentrations and daily hospital admissions for respiratory causes. These studies have consistently shown an apparent linear relationship in various North American locations between ozone and the admissions, and EPA has <u>assumed</u> that this relationship is cause and effect. The relationship has been shown to remain even when considering only concentrations below the present NAAQS. Thus, there is no evidence of a threshold concentration and this reinforces the conclusion from the field studies.

CASAC'S INTERPRETATION AND RECOMMENDATIONS ON OZONE

It was the consensus of the CASAC Panel that there only be one primary NAAQS, either an

8-hour or a 1-hour NAAQS. Even though an 8-hour time-frame appeared to be a better measure of response, the Panel acknowledged that the same degree of public health protection could be achieved with either an 8-hour or a 1-hour NAAQS at the appropriate level. It was also the consensus of the Panel that the form of the new standard be more robust than the present one. The present standard is based on an extreme value statistic which is significantly dependent on stochastic processes such as extreme meteorological conditions. The result is that areas which are near attainment will randomly flip in and out of compliance. A more robust, concentration-based form will minimize the "flip-flops," and provide some insulation from the impacts of extreme meteorological events.

The Panel felt that the weight of the health effects evidence indicates that there is no threshold concentration for the onset of biological responses due to exposure to ozone above background concentrations. Based on information now available, it appears that ozone may elicit a continuum of biological responses down to background concentrations. It is critical to understand that a biological response does not necessarily imply an adverse health effect. Nevertheless, this means that the paradigm of selecting a standard at the lowest-observable-effects-level and then providing an "adequate margin of safety" is not possible. It further means that risk assessments must play a central role in identifying an appropriate level.

To conduct the risk assessments, EPA had to identify the populations at risk and the physiological responses of concern, develop a model to estimate the exposure of this population to ozone, and develop a model to estimate the probability of an adverse physiological response to the exposure. EPA selected a small segment of the population, "outdoor children" and "outdoor workers," particularly those with preexisting respiratory disease as the appropriate populations with the highest risks. The Panel concurred with the Agency that the models selected to estimate exposure and risk were appropriate models. However, because of the myriad of assumptions that are made to estimate population exposure and risk, large uncertainties exist in the model estimates.

The results of two of the risk analyses are presented in the Staff Paper[6] and are reproduced in Tables 3 and 4. It should be noted that the numbers in these Tables differ slightly from the numbers presented in the closure letter[8] which were based on EPA's estimates that were in the August 1995 draft of the Staff Paper. The numbers in Tables 3 and 4 are based on EPA's latest estimates contained in the final June 1996 Staff Paper. The biggest change is in the total number of asthma hospital admissions in Table 4 which is 50% lower than those in the closure letter. The difference is that the closure letter used annual admissions, but the numbers in Table 4 are six-month (ozone season) numbers. By using a six-month basis for the total admissions, the percentage of annual admissions due to ozone exposure is inflated by a factor of two.

The ranges from ten model runs of the risk estimates across nine cities for outdoor children are presented in Table 3. Because of the large number of stochastic variables used in the exposure model, the exposure estimates vary from run to run. However, the ranges presented in Tables 3 and 4 are not reflective of all of the uncertainties associated with the numerous assumptions that were made to develop the estimates.

Based on the results presented in these and other similar tables presented in the Staff Paper and an acknowledgment that all the uncertainties cannot be quantified, the CASAC Panel concluded that there is no “bright line” which distinguishes any of the proposed standards (either the level or the number of allowable exceedances) as being significantly more protective of public health (this includes the present standard). For example, the differences in the percent of outdoor children (Table 3) responding between the present standard (1H1EX at 0.12 ppm) and the most stringent proposal (8H1EX at 0.07 ppm) are small and their ranges overlap for all health endpoints. In Table 4, the estimates in row 1 suggest considerable differences between the several options. However, when ozone-aggravated asthma admissions are compared to total asthma admissions (rows 5 and 6), the differences between the various options are small.

The results in Table 4 also raise questions concerning the reasonableness of the assumption of a linear relationship between admissions and ozone concentrations with no threshold concentration. If New York City was just meeting the present NAAQS of 0.12 ppm (1H1EX 0.12), Table 4 indicates that ozone would be responsible for 890 admissions per year. However, of that 890, only 210 admissions would be due to ozone concentrations above the summer background concentration which is taken here to be 0.04 ppm. The majority, 680, or 76.4% of the admissions are attributable to ozone exposure when the ozone concentrations were less than or equal to the summertime background.

Nevertheless, the CASAC Panel could see no “bright line” to use as a guide in selecting the numerical value of an NAAQS. However, some of the members did express personal preferences for the level of the 8-hour NAAQS and they are given below. All the members recommended that there be multiple allowable exceedances. Two other members said that the selection of a level is strictly a policy decision since the risk assessment did not show that any of the NAAQSs considered were more protective of public health. The health effects experts were equally divided as well. Clearly, this is not an endorsement for a 0.08 ppm standard.

# of Members	Preference
1	0.09-0.10
3	0.09
1	0.08-0.09
3	0.08
2	policy call

PERSPECTIVE ON OZONE

Let us examine the individual recommendations of the panel members. Of the fifteen panel members, ten expressed an opinion on the level of the primary NAAQS. Of the five members who did not express an opinion, four were plant biologists who were on the panel for their expertise regarding the secondary NAAQS issue and they were not expected to comment on the primary NAAQS. A fifth panelist, an atmospheric scientist, gave the panel guidance on atmospheric issues but chose not to participate in the health effects discussions.

Of the ten who voiced an opinion, all endorsed an 8-hour standard and all endorsed multiple exceedances. Three members recommended 0.08 ppm which is clearly *more* stringent than the present NAAQS. Three other members recommended 0.09 ppm and one member recommended a range of 0.09 to 0.10 ppm which, with multiple allowable exceedances, ranges from a NAAQS *equal* in stringency to the current NAAQS to a NAAQS *less* stringent to the current NAAQS. Two other members (including the author) said it is a policy decision because the science has not shown any of the alternatives that are being considered as being more protective of public health than any other. The last member supported a NAAQS in the "higher end, the middle to higher end."

THE PM REVIEW PROCESS

The major steps in the PM NAAQS review process are illustrated in Table 5. EPA began drafting the PM Criteria Document[9], in the middle of 1994 Recent Criteria Documents have become mammoth undertakings. The first PM Criteria Document,[10] published in 1969, summarized the relevant science in 220 pages. The final version of the present Criteria Document is a three volume set containing over 2400 pages.

The Staff Paper[11] (Staff Paper) contains the Agency's recommendations for the range and form of the NAAQS along with justifications that are drawn from material contained in the Criteria Document. In the past, the CASAC review of a Criteria Document was completed before the Staff Paper was written so that the Staff Paper would reflect the science contained in the final Criteria Document (an exception to this was the recent ozone review[1]). The reviews of both the Criteria Document and Staff Paper are iterative processes that usually involve two to three revisions to both of the documents before CASAC reaches closure, and, in the past, the entire process took several years to complete. However, this review was on an accelerated schedule because of a court order resulting from a lawsuit filed by the American Lung Association (ALA).

In February 1994, the ALA filed a suit to compel EPA to complete the PM review by December 1995. The U.S. District Court for the District of Arizona[12] subsequently ordered EPA to complete its review and propose any revision in the *Federal Register* by June 30, 1996 with final promulgation by January 31, 1997. In addition, the Court adopted EPA's projection that the CASAC review of the Criteria Document should be completed by the end of August 1995. Further, the Court ordered EPA to complete a first draft of the Staff Paper by June 1995 and gave CASAC three months to complete its review of the Staff Paper. In addition, the Court stated: "The Court excludes from its revised schedule, the EPA's provisions for interim CASAC review of various Criteria Document and Staff Paper drafts, including participation by CASAC in the development of methodologies for assessment of exposure/risk analyses." As you will see below, however, the review did deviate somewhat from this schedule.

The CASAC Panel members met to discuss the draft of the Criteria Document on August 3-4, 1995, but they could not come to closure. The panel felt that the Criteria Document required extensive revisions and recommended that it be given the opportunity to review the revised draft.[13] As a result, both EPA and the ALA petitioned the Court and were granted an extension allowing CASAC until January 5, 1996 to complete its review of the Criteria Document and Staff Paper. CASAC met again on December 14-15, 1995 to review the revised draft of the Criteria Document and the first draft of the Staff Paper. Again the Panel concluded that the Criteria Document did "not provide an adequate review of the available scientific data and relevant studies of PM," and could not come to closure on either the Criteria Document or the Staff Paper.[14] Again, both EPA and the ALA petitioned the Court and were granted an extension allowing CASAC until March 15, 1996 to complete its review of the Criteria Document and June 15, 1996 to complete it review of a revised Staff Paper. At a February 29, 1996, the CASAC Panel succumbed to the pressures exerted by the accelerated schedule and reluctantly came to closure on the Criteria Document. I say reluctantly because in the closure letter[15] it was stated that "a number of members have expressed concern that since we are closing on the Criteria Document before we will be able to see the revised version, we have no assurance that our comments will be incorporated." Nevertheless, the Panel closed on the Criteria Document on March 15, 1996.

On May 16 and 17, the Panel met for the final time to review the revised Staff Paper, and came to closure[16]. The details of this review and the CASAC recommendations will be discussed shortly.

HISTORY OF THE PM STANDARDS

The history of the PM standards is summarized in Table 6. In 1971, EPA set annual average and 24-hour NAAQSs for total suspended particulates (TSP). Total suspended particulates consisted of any PM that was collected on the filter of a high volume sampler operating within certain EPA specifications. The upper size captured by the high volume sampler varied with wind speed and wind direction but was generally limited to PM with diameters less than 40 µm (the width of a human hair is about 70 µm). Between 1971 and 1987, it was realized that the most important PM, from a health perspective, were those that deposited in the deep lung (tracheobronchial or pulmonary) region of the of the respiratory system. Maximum PM penetration to the deep lung region occurs during oronasal (combined nose/mouth breathing) or mouth breathing and deposition is restricted to those PM equal to or less than 10 µm in diameter. In nasal breathing, deep lung deposition is limited to particles less than or equal to about 1 µm in diameter. Consequently, in 1987, EPA replaced the TSP NAAQSs with 24-hour and annual PM_{10} NAAQSs where PM_{10} refers to those particles that are equal to or less than 10 µm in diameter. Operationally PM_{10} is defined by the Federal Reference method and sampler. In terms of sampler collection efficiency, the 10 µm cut point represents the size of the particle that is collected with a 50% collection efficiency.

The PM NAAQS is the only NAAQS that is not chemically specific although it is understood that the toxicity of individual particles are not equal. Furthermore, it is understood that the potential for biological responses varies with particle size. As mentioned above, for normal nasal breathing, the particle sizes of concern are generally 1 µm in diameter or less, while for oronasal breathing, particles equal to or less than 10 µm in diameter are of concern. In addition, the sources of the fine particles ($PM_{1.0}$ or $PM_{2.5}$) are generally different from the sources of the coarser particles (particles greater than or equal to 2.5 µm in diameter. For example particles less than 2.5 µm in diameter are formed primarily by combustion or secondary chemical reactions in the atmosphere whereas particles greater than or equal to 2.5 µm in diameter are formed primarily by mechanical processes (construction, demolition, unpaved roads, wind erosion, etc.) For these reasons, many have felt that fine and coarse particles should be treated as separate pollutants because different control strategies are required to address both size ranges. This logic and the health effects discussed below are what lead EPA staff to recommend the separate $PM_{2.5}$ and PM_{10} NAAQSs listed in Table 6.

The proposed $PM_{2.5}$ NAAQSs is considerably more stringent than the existing PM10 NAAQS. Based on 1993-95 PM_{10} data, there are 41 U.S. counties with monitors not meeting either the annual or 24-hr $PM_{2.5}$ NAAQSs. Under the new $PM_{2.5}$ NAAQSs proposals, it is estimated that the nonattainment counties would be about 170. However, there are two caveats. First, very few places have $PM_{2.5}$ monitors. Consequently $PM_{2.5}$ data are estimated. The $PM_{2.5}$ concentrations were estimated for all counties with PM_{10} samplers by multiplying the relatively abundant PM_{10} data by ratios derived from a much more limited $PM_{2.5}/PM_{10}$ data base. Second, these estimates only include counties with PM_{10} monitors. It is likely, that there will be significant numbers of counties currently without monitors that will eventually be found to be out of attainment. As a consequence, the actual number of PM nonattainment areas will be substantially higher than EPA's estimates.

PM HEALTH EFFECT STUDIES: RESULTS AND IMPLICATIONS

Although individual PM health effect studies have focused on a variety of endpoints, for obvious reasons the epidemiology studies that focused on human mortality were the primary focus of this review. Consequently, we will only discuss these studies.

There were two types of PM-mortality studies cited by EPA. The first were the short-term, acute mortality studies which compared the daily PM and mortality time series in a dozen or so locations around the US. After filtering out or accounting for the effects of such things as seasonality, day of the week, meteorology, etc. on mortality, the remaining statistical relationship between daily PM and daily mortality was quantified. Although this relationship varied from location to location, the average value was a 4% increase in daily deaths for a 50 $\mu g/m^3$ increase in PM_{10} concentrations.

The second type of epidemiological study is the long-term prospective cohort studies where the health status of certain groups (cohorts) of individuals is followed for a number of years in various locations around the country. In these studies, the annual mortality rate in a given location is related to the annual average PM_{10} or $PM_{2.5}$ concentrations after the mortality rates have been adjusted for smoking and some other potential confounding variables. Of the three studies reported in the literature, two show a positive relationship between annual mortality and PM and attribute two to three times the number of deaths to PM as the short-term acute effect studies. The third study shows no PM-mortality relationship but EPA dismissed this study for a number of reasons including its lower statistical power (smaller sample size). EPA uses higher mortality estimates from the two studies to conclude that there are premature deaths due to chronic exposure to PM in addition to the deaths due to acute exposures identified in the time-series studies.

In addition, EPA also concluded that the mortality was due to $PM_{2.5}$ rather than the coarse fraction of the PM_{10}. As will be discussed below, the evidence for this conclusion was ambiguous.

CASAC'S INTERPRETATION AND RECOMMENDATIONS ON PM

Table 7 summarizes the Panel members' recommendations concerning the forms and levels of the primary standards. Although some Panel members preferred to have a direct measurement of coarse mode PM ($PM_{10-2.5}$) rather than using PM_{10} as a surrogate for it, there was a consensus that retaining an annual PM_{10} NAAQS at the current level is reasonable at this time. A majority of the members recommended keeping the present 24-hour PM_{10} NAAQS, although those commenting on the form of the standard strongly recommended that the form be changed to one that is more robust than the current standard to provide some insulation from the impacts of extreme meteorological events. Because of the acceptance that $PM_{10-2.5}$ and $PM_{2.5}$ are different pollutants, there was also a consensus that a new $PM_{2.5}$ NAAQS be established, with nineteen Panel members endorsing the concept of a 24-hour and/or an annual $PM_{2.5}$ NAAQS. The remaining two Panel members did not think any $PM_{2.5}$ NAAQS was justified. However, as indicated in Table 7, there was no consensus on the level, averaging time, or form of a $PM_{2.5}$ NAAQS. At first examination of Table 7, the diversity of opinion is obvious and appears to defy further characterization. However, the opinions can be classified into several broad categories. Four Panel members supported specific ranges or levels within or toward the lower end of EPA staff's recommended ranges. Seven Panel members supported specific ranges or levels near, at, or above the upper end of staff's recommended ranges. Two members did not think a $PM_{2.5}$ NAAQS was warranted at all. The remaining eight other Panel members endorsed the concept of a $PM_{2.5}$ NAAQS, but declined to select a specific range or level. Consequently, only a minority of the Panel members supported a range that includes the present EPA proposals.

I would like to emphasize that CASAC did <u>not</u> endorse EPA's recommended ranges. Pertaining to the 24-hour $PM_{2.5}$ NAAQS, only five members recommended a range that was within EPA's recommended range. Four members recommended greater than or equal to the top of EPA's range. Four members did not recommend a 24-hour NAAQS. The remaining eight members merely endorsed the concept of a 24-hour $PM_{2.5}$ NAAQS, but declined to select a value or range (see footnote 2 in Table 7). Also note from Table 7 that the diversity of opinion was exhibited by the health experts as well as the non-health experts. Clearly, this was not an endorsement of EPA's recommended range.

For the annual standard, four members favored a range or value that was within EPA's recommended range. Three members favored a higher range and eight did not think an annual $PM_{2.5}$ NAAQS was needed. The remaining six members merely endorsed the concept of an annual standard but declined to select a value or range. Again, note from Table 7 that the diversity of opinion was exhibited by the health experts as well as the non-health experts. Clearly, this also was not an endorsement of EPA's recommended range.

However, most of the members who declined to recommend a range had caveats which appear as footnotes in Table 7. The caveats include: "recommends a more robust 24-hr. form," "concerned upper range is too low based on national $PM_{2.5}/PM_{10}$ ratio," "leans towards high end of EPA's proposed range," "yes, but decision not based on epidemiological studies," "low end of EPA's proposed range is inappropriate; desires levels selected to include areas for which there is broad public and technical agreement that they have $PM_{2.5}$ pollution problems," "only if EPA has confidence that reducing $PM_{2.5}$ will indeed reduce the components of particles responsible for their adverse effects," and "concerned lower end of range is too close to background."

The diversity of opinion expressed by the Panel members reflected the many unanswered questions and large uncertainties associated with establishing causality of the association between $PM_{2.5}$ and mortality. Most Panel members were influenced, to varying degrees by these unanswered questions and uncertainties. The concerns include but are not limited to: 1) the influence of confounding variables, 2) measurement errors, 3) the existence of possible alternative explanations, 4) the lack of an understanding of toxicological mechanisms, 5) the fraction of the daily mortality that is advanced by a few days because of pollution, 6) exposure misclassification, 7) the shape of the dose-response function, and 8) the use of different models in all the studies. Let me expand on these issues.

The first three concerns are related because they pertain to how certain we are that we have identified the correct causative agent. As mentioned earlier, PM_{10} and $PM_{2.5}$ are not single chemical entities. They are composed of four or five major constituents and hundreds of trace constituents. Some have suggested that the causative agent could be some constituent of the PM rather than the total PM or total $PM_{2.5}$ which would require a control strategy targeted at the causative constituent rather than at PM_{10} or $PM_{2.5}$ in general. Also because many of the PM constituents are highly correlated (also with some of the gaseous pollutants as well), the regression methodologies used to determine association, tend to select those variable with the smallest measurement error. For example, $PM_{2.5}$ and PM_{10} are measured much more precisely than the coarse fraction of the PM_{10} ($PM_{10-2.5}$). Consequently, the slightly higher relative risk calculated from the statistical models for $PM_{2.5}$ (versus $PM_{10-2.5}$) is not proof that $PM_{10-2.5}$ is not the causative agent. Finally, several studies including some of the recent reanalyses of original studies have included gaseous criteria pollutants in their model and discovered that in many cases ozone, sulfur dioxide or carbon monoxide can be as important, and in some cases, more important that PM in describing the mortality. When the data bases are segregated by season, even more confusing results occur as different pollutants are identified for each season as being the apparent causative agent. This has led some to conclude that it is overall air pollution that is causing the excess mortality and that PM is just a surrogate measure. If that is the case, it does not necessarily follow that reducing the concentrations of a surrogate will result in reduced mortality.

The fourth issue of concern has caused several of the Panel members, including one of the chest physicians to state that there is no biologically plausible mechanism that could explain the apparent relationship between acute mortality and PM at concentrations that are a fraction of the present PM_{10} NAAQSs. This has lead some to postulate that the acute mortality is actually a “harvesting” effect. That is, individuals who are terminally ill die somewhat prematurely due to the additional stress caused by PM or overall air pollution. While this may explain some or most of the acute deaths, it can not explain the apparent long-term, chronic deaths attributed to annual PM concentrations in the prospective cohort studies. These prospective cohort studies suggest that the acute mortality only accounts for about a third to a half of the total deaths attributed to PM. However, all or most of this discrepancy vanishes when additional potentially confounding variables are included in the cohort studies and historical or cumulative rather than concurrent air pollution exposures are considered.

The exposure misclassification concern revolves around the validity of the assumption made in all of the acute studies that daily ambient PM data collected from a centrally located air monitoring site is representative of personal exposure to PM. Results from studies which examined this assumption are ambiguous. The shape of the dose-response function is also a concern. Because of measurement errors, the present statistical methodologies are incapable of detecting the existence of a possible threshold concentration below which acute mortality would not occur. Finally, there is some concern because the statistical models used in the various geographical areas are different. At different sites, different combinations of variables, averaging times, methods for accounting for seasonality and meteorology, and lag times have been used to produce the reported PM-mortality relationships.

The lack of consensus on many of these issues can be partially attributed to the accelerated review schedule. The deadlines did not allow adequate time to analyze, integrate, interpret, and debate the available data on this very complex issue. Nor did the court-ordered schedule recognize that achieving the goal of a scientifically defensible NAAQS for PM may require iterative steps to be taken in which new data are acquired to fill obvious and critical voids in our knowledge. The previous PM NAAQS review took eight years to complete.

The Panel was unanimous, however, in its desire to avoid a similar situation when the next PM NAAQS review cycle is under way by a future CASAC Panel. CASAC strongly recommended that EPA immediately implement a targeted research program to address these unanswered questions and uncertainties. It is also essential that long-term $PM_{2.5}$ measurements are obtained. CASAC volunteered to assist EPA in the development of a comprehensive research plan that will address the questions which need answers before the next PM review cycle is completed.

PERSPECTIVE

Since PM_{10} measurements became widespread in 1988, significant and continuous declines in ambient PM_{10} concentrations have been observed throughout the U.S. Nationwide PM_{10} concentrations have declined 22% from 1988 to 1995.[17] The reason for this decline is because of the implementation of existing control programs required by the 1990 Clean Air Act Amendments that target $PM_{2.5}$ precursors (VOCs, NO_x, and SO_2), diesel PM emissions and other primary emission sources. This trend will continue for the foreseeable future as additional measures required by the Amendments are phased in. Consequently, there is time to conduct the research recommended by CASAC which targets the concerns discussed above. Then appropriate $PM_{2.5}$ NAAQSs could be established.

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Table 1: Steps in the NAAQS review process. Completion dates are for the ozone review

	Steps in a NAAQS Review	Completion Date
1	CASAC review of the Criteria Document	June 1994 to September 1995
2	CASAC closure on Criteria Document	November 28, 1995
3	CASAC review of Staff Paper	February 1995 to September, 1995
4	CASAC closure on Staff Paper	November 30, 1995
5	EPA publishes proposed NAAQS in Federal Register	December 13, 1996
6	EPA promulgates final NAAQS in Federal Register	July 19, 1997

Table 2: Historical Overview of Ozone NAAQS

Year	Primary NAAQS	Secondary NAAQS
1971	1-hr. @ 0.08 ppm	same as primary
1977	1-hr. @ 0.12 ppm 3 ex in 3 years*	same as primary
1993	reaffirmed 1977 NAAQS	reaffirmed 1977 NAAQS
1996 (recommended in Staff Paper)	8-hr. @ 0.07-0.09 ppm 1 to 5 ex per year averaged over 3 years**	3 month SUM06 25-36 ppm-hours#
December 13, 1996 proposal	8-hr @ 0.08 ave of 3rd highest in 3 yrs	either equal to primary or 3-mo SUM06 @ 25 ppm-hours

* 3 exceedances allowed within 3 consecutive years
** 1 to 5 exceedances allowed within a year averaged over a 3-year period
# see Criteria Document[5] for an explanation

Table 3: Range of Median Percent of Outdoor Children Responding Across Nine U.S. Urban Areas Upon Attaining Alternative Air Quality Standards.[a]

Health Endpoints	Range of Median Risk Estimates Associated With Just Attaining Alternative Standards (percent of outdoor children responding)							
	Alternative 1-Hour NAAQS		Alternative 8-Hour Daily Maximum Standards					
			1 Expected Exceedance Standards				5 Expected Exceedance Stanc	
	1H1EX[b] 0.12 ppm	1H1EX 0.10 ppm	8H1EX 0.10 ppm	8H1EX 0.09 ppm	8H1EX 0.08 ppm	8H1EX 0.07 ppm	8H5EX 0.09 ppm	8H5EX 0.08 ppm
FEV$_1$ decrement \$ 15%	5-14	3-9	7-16	5-12	3-8	2-5	5-14	3-10
FEV$_1$ decrement \$ 20%	1-6	0-4	2-7	2-5	1-3	0-1	2-6	1-4
Moderate or Severe Pain on Deep Inspiration	0	0	0-1	0	0	0	-	-
Moderate or Severe Cough	0-1	0	0-1	0-1	0	0	-	-

[a] Estimates for alternative NAAQSs with 1 exceedance from Table V-18 in final Staff Paper[6]; estimates for NAAQSs with 5 exceedances from Table VI-1 in August 1995 draft Staff Paper.

[b] 1H means 1-hour standard; 1EX means 1 allowable exceedance per year.

Table 4: Estimated Hospital Admissions for Asthmatics in the New York City Area

	1H1EX 0.12	**1H1EX 0.10**	**8H1EX 0.10**	**8H1EX 0.09**	**8H1EX 0.08**	**8H1EX 0.07**	**8H5EX 0.09**	**8H5EX 0.08**	**AS IS**
Excess Admissions[a]	207 70-344	130	240	180	115 39-191	60	180	120 41-199	388 132-644
%) from present std	0%	-37%	+16%	-13%	-44%	-71%	-13%	-42%	+87%
Excess + background[b]	909 308- 1509	810	920	860	804 273- 1336	740	860	797 270- 1320	1065 361- 1770
%) from present standard	0%	-11%	+1%	-5%	-12%	-19%	-5%	-12%	+17%
All Asthma Admissions	14,819	14,742	14,852	14,792	14,727	14,672	14,792	14,732	15,000
%) from present standard	0%	-0.5%	+0.2%	-0.2%	-0.6%	-1.0%	-0.2%	-0.6%	+1.2%

a - excess asthma admissions attributed to ozone levels exceeding a background concentration of 0.04 ppm; the values with ranges (90% confidence intervals) are from Table V-20 in the Staff Paper[6]; single value estimates are from Figure V-17 in the Staff Paper[6]

b - asthma admissions included in (a) plus those due to background ozone concentrations; admissions due to background = 1065 - 388 = 677

Table 5: Steps in the NAAQS review process. Completion dates are for the PM review

	Steps in a NAAQS Review	Completion Date
1	CASAC review of the Criteria Document	June 1995 to March 1996
2	CASAC closure on Criteria Document	March 15, 1996
3	CASAC review of Staff Paper	November 1995 to June 1996
4	CASAC closure on Staff Paper	June 13, 1996
5	EPA publishes proposed NAAQS in Federal Register	December 13, 1996
6	EPA promulgates final NAAQS in Federal Register	July 19, 1997

Table 6: Historical Overview of PM NAAQSs

YEAR	MEASURE	24-HR ($\mu g/m^3$)	ANNUAL ($\mu g/m^3$)
1971	total suspended particulates (TSP)	260	75
1987	PM_{10} (particulates with diameters # 10 μm)	150	50
1996	*EPA Staff recommendation*: $PM_{2.5}$ PM_{10}	 18-65 150	 12.5-20 40-50
12/96	*Federal Register* Notice $PM_{2.5}$ PM_{10}	 50 150	 15 50

Table 7: Summary of CASAC Panel Members Recommendations

(all units µg/m^3)

	$PM_{2.5}$	$PM_{2.5}$	PM_{10}	PM_{10}
	24-hr	**Annual**	**24-hr**	**Annual**
EPA Staff Recommendation	18 -65	12.5 - 20	150[13]	40 - 50
December, 1996 Proposal	50	15	150	50
Discipline of Panel Member				
Epidemiologist[1]	20 - 50	no	no	40 - 50
Epidemiologist	20 - 30	15 - 20	no	50
Health Effects Expert	20 - 50[3]	15 - 20	no	40 - 50
Atmospheric Scientist	20 - 50[3]	20 - 30	no	40 -50[4]
Biologist	yes[2]	yes[2]	150	50
Chest Physician	yes[2]	yes[2]	150	50
Atmospheric Scientist	yes[2,3,12]	yes[2,5]	150[3,13]	50
Atmospheric Scientist	yes[2,9]	yes[2,9]	yes[4]	yes[4]
Atmospheric Scientist	yes[3,10]	yes[10]	no[3,4]	yes[4]
Epidemiologist[1]	yes[2,11]	no	150	yes[2]
Atmospheric Scientist	yes[3,5]	no	150[13]	50
Atmospheric Scientist	yes[2,5,6,12]	yes[2,5,6]	no	yes[4]
Toxicologist	50	20	150	50
Atmospheric Scientist	no	20	150	50
Statistics Expert	no	25-30[7]	no	yes[2]
Chest Physician	65	no	150	50
Epidemiologist	75[7]	25-30[7]	150	50
Biologist	75	no	150	40 - 50
Atmospheric Scientist[*]	75[3,7]	no	150[3]	50
Toxicologist	no[8]	no[8]	150	50
Toxicologist	no	no	150	50

[1]not present at meeting; recommendations based on written comments

[2] declined to select a value or range

[3]recommends a more robust 24-hr. form

[4]perfers a $PM_{10-2.5}$ standard rather than a PM_{10} standard

[5] concerned upper range is too low based on national $PM_{2.5}/PM_{10}$ ratio

[6] leans towards high end of EPA's proposed range

[7] desires equivalent stringency as present PM_{10} standards

[8] if EPA decides a $PM_{2.5}$ NAAQS is required, the 24-hr. and annual standards should be 75 and 25 µg/m^3, respectively with a robust form

[9] yes, but decision not based on epidemiological studies

[10] low end of EPA's proposed range is inappropriate; desires levels selected to include areas for which there is broad public and technical agreement that they have $PM_{2.5}$ pollution problems

[11] only if EPA has confidence that reducing $PM_{2.5}$ will indeed reduce the components of particles responsible for their adverse effects

[12] concerned lower end of range is too close to background

[13] the annual standard may be sufficient; 24-hour level recommended if 24-hour NAAQS is retained

[*] the chair's recommendation